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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,874	09/30/2003	Howard Bernstein	17976-0006	6790

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,874	BERNSTEIN ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-35 and 37-56* is/are rejected.

7)☒ Claim(s) *13,23 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-56 are pending in this application.

Action Summary

1. The rejection of claim 13 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn as applicant has corrected the claim dependency to overcome the indefiniteness.

2. The rejection of claims 1-7, 10-12, 14-21, 27, 30, 32-36, 38-48 and 50-53 under 35 U.S.C. 102(a) as being anticipated by Edwards et al. is hereby withdrawn in view of applicants amendment.

3. The rejection of claims 1-11, 14-35 and 37-56 under 35 U.S.C. 102(e) as being anticipated by Straub et al. is hereby withdrawn in view of applicants amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-11, 14-35 and 37-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US 6,395,300).

Applicants claim a sustained release formulation comprising porous microparticles, which comprise a pharmaceutical agent and matrix, wherein the microparticles have a geometric size of 0.1 to 5 microns and an average porosity of between 15% and 90% by volume.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Straub et al. discloses a porous drug matrix additionally comprising water-soluble polymers or sugars, wetting agents such as surfactants, etc. and the matrix having a diameter size of about 100 nm to 5 microns (col. 3, lines 46-61). Column 4, line 11 through column 8, line 9 list the types of drugs that can be employed in the drug matrix. Column 8, lines 34-67 teach examples of the polymers and sugars that can be used in the matrix such as polyvinylpyrrolidone (line 41), xylitol (line 59) and lactose (line 63). Column 11, line 47 through column 12, line 33 teach a method of making the porous drug matrix. Column 12, lines 46-67 teach examples of the surfactants to be employed in the matrix such as phospholipids like lecithins. Column 13, lines 29-41 teaches that the preferred embodiment of the invention is drug matrix in the form of a powder which

can be reconstituted with an aqueous medium or using the powder formulation in a dry powder inhaler.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art does not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed or the average porosity volume of 5% to 90% by volume.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

Although, prior art reference of Straub et al. does not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed by applicant, it is the position of the examiner that this limitation is inherent in the formulation as claimed. The composition as claimed is directed toward porous microparticles comprising a pharmaceutical agent and a matrix material. Since there is no additional information in the specification with regards to the release profile (i.e. coating or physical makeup which makes it a sustained release), any porous microparticle having the claimed drug and matrix material would have the release profile as claimed. The determination of the average porosity volume would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art when formulating a porous particle for the sustained release of a drug would have determined

that the amount of pores on the particles would have an effect on the delivery of the drug; the more pores the greater the delivery of the drug over a period of time; the less amount of pores the less the delivery of the drug over the same period of time.

Response to Arguments

5. Applicant's arguments filed December 13, 2006 have been fully considered but they are not persuasive.

Applicants argue that Straub et al. does not disclose "wherein the combination of the pharmaceutical agent, matrix material, geometric size and average porosity are selected to provide that upon inhalation the...". It is the position of the examiner that this limitation is functional language, describing why the combination was selected. This recitation carries no patentable weight.

Allowable Subject Matter

6. Claims 12, 13 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the matrix polymer selected from those listed from those listed in claims 12 and 13. It is also not taught using the formulation to treat or control asthma.

Conclusion

7. Claims 1-11, 14-35 and 37-56 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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